52. A method for regulating cytokine production, inducing nitrogen monoxide production, suppressing allergy, or suppressing IgE production, which comprises administering an effective amount of the cosmetic composition of claim 48 to a subject in need thereof for regulating cytokine production, inducing nitrogen monoxide production, suppressing allergy, or suppressing IgE production.--

REMARKS

Status of the Claims

Claims 1-27 are cancelled without prejudice or disclaimer of the subject matter contained therein. Claims 28-52 are added. Claim 28 corresponds to cancelled claim 22, wherein the limitation related to fucoidan is amended to "fucoidan derived from Kjellmaniella crassifolia." Support for this phrase is found on page 8, line 6 of the specification. Claims 29-32 correspond to cancelled claims 24-27. Claim 33 corresponds to cancelled claim 16, wherein the limitation related to fucoidan is amended to "fucoidan derived from Kjellmaniella crassifolia." Claims 34-38, which depend from claim 33, correspond to

cancelled claims 3-7. Claim 39 corresponds to cancelled claim 20, wherein the limitation related to fucoidan is amended to "fucoidan derived from Kjellmaniella crassifolia." Claims 40-42, which depend from claim 39, correspond to cancelled claims 3-5. Also, an embodiment in which food, drink or feed containing the fucoidan and/or a degradation product thereof as an effective ingredient is recited as a claim 43. In addition, an embodiment in which a cosmetic containing the fucoidan and/or a degradation product thereof as an effective ingredient is recited in claim 44. Claims 43 and 44 depend from claim 39, respectively. Claims 45 and 46 are supported by claim 28 and the description on page 22 of the specification. Claims 47-48 are supported by the description on page 36 of the specification. Claims 49-52 are supported by the above-mentioned portions of the specification supporting claims 33, 39, 45 and 48.

Claim Objections

Claims 3-5, 7, 8 and 10 are objected to as being substantial duplicates of claim 1 for the reasons set forth in the second full paragraph on page 2 of the Office Action. This rejection is moot in view of the cancellation of claims 1, 3-5, 7, 8 and 10.

Obviousness-Type Double Patenting Rejections

Claims 22 and 24-27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claim 1 of copending Application No. 10/148,486 (US 2002/0039670) for the reasons in the last paragraph on page 2 of the Office Action. Claims 8 and 10-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claim 9 of copending Application No. 10/148,486 (US 2002/0039670) for the reasons on pages 3-4 of the Office Action. These rejections are respectfully traversed.

These rejections are believed to be moot, in part, in view of the cancellation of claims 8 and 10-13. However, with respect to claims 22 and 24-27, corresponding to claims 28-32, the Examiner is respectfully requested to hold these rejections in

abeyance until one of the applications is allowed in accordance with PTO procedures. See MPEP 804 at page 800-19.

Rejection Under 35 U.S.C. 101

Claims 14, 15, 18, 19 and 21 are rejected by the Examiner under 35 U.S.C. 101 for the reasons set forth in the last paragraph on page 4 through the first paragraph on page 5 of the Office Action. This rejection is respectfully traversed.

Reconsideration and withdrawal thereof are requested.

This rejection is moot in view of the cancellation of claims 14, 15, 18, 19 and 21.

Rejection Under 35 U.S.C. 112, Second Paragraph

Claims 14, 15, 18, 19 and 21 are rejected by the Examiner under 35 U.S.C. 112, second paragraph, for the reasons set forth in the last two paragraphs on page 5 of the Office Action. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

This rejection is moot in view of the cancellation of claims 14, 15, 18, 19 and 21.

Rejection of Claims 1-13, 15, 17-19 Under 35 U.S.C. 102(e) Over Umeda et al.

Claims 1-13, 15 and 17-19 are rejected by the Examiner under 35 U.S.C. 102(e) over Umeda et al. for the reasons set forth on page 6 through the first two lines on page 7 of the Office Action. This rejection is respectfully traversed.

Reconsideration and withdrawal thereof are requested.

This rejection is moot in view of the cancellation of claims 1-13, 15 and 17-19.

Rejection of Claims 22-27 Under 35 U.S.C. 102(a) Over TAKO (WO 99/01478)

Claims 22-27 are rejected by the Examiner under 102(a) over TAKO (WO 99/01478) for the reasons set forth on page 7 of the Office Action. This rejection is respectfully traversed.

Reconsideration and withdrawal thereof are requested.

Cancelled claims 22-27 correspond to claims 28-32, wherein the limitation previously relating to fucoidan is clarified to be directed to a fucoidan derived from *Kjellmaniella crassifolia*.

That is, claim 28 relates to a cosmetic for regulation of cytokine production, induction of nitrogen monoxide production, or anti-allergy, characterized in that the cosmetic comprises as

an effective ingredient a fucoidan derived from *Kjellmaniella* crassifolia and/or a degradation product thereof.

The TAKO reference only discloses applicability for a cosmetic of acetylfucoidan derived from Cladosiphon okamuranus TOKIDA. Specifically, the Examiner's attention is directed to the section labelled TECHNICAL FIELD on page 1, lines 6-12 of the TAKO reference, which is reproduced for the Examiner's convenience as follows:

"TECHNICAL FIELD

This invention relates to a technique for conveniently preparing novel, high-purity acetylfucoidan containing acetic acid, derived from natural or cultured *Cladosiphon okamuranus TOKIDA*, which can be utilized as ... cosmetics, biotechnologies and other industrial use."

The Examiner should note that fucoidan derived from Kjellmaniella crassifolia is different than acetylfucoidan derived from Cladosiphon okamuranus TOKIDA, so that the inventions of claims 28-32 are fundamentally different from the invention disclosed in the TAKO reference. Accordingly, the rejection over the TAKO reference (WO 99/01478) for the reasons set forth on page 7 of the Office Action should be withdrawn by the Examiner.

Moreover, the Examiner should note that an embodiment in which a cosmetic containing the fucoidan and/or a degradation product thereof as an effective ingredient is recited in claim 44, which depends from claim 39. However, since the fucoidan of the claim 44 is a fucoidan derived from *Kjellmaniella* crassifolia, the invention of the claim 44 cannot be anticipated by the teachings of the TAKO reference.

Rejection of Claims 14, 16, 20 and 21 Under 35 U.S.C. 102(e) Over Parish et al.

Claims 14, 16, 20 and 21 are rejected by the Examiner under 102(e) over Parash et al. for the reasons set forth on page 7 of the Office Action. This rejection is respectfully traversed.

Reconsideration and withdrawal thereof are requested.

Claims 14 and 21 are canceled. Also, the fucoidan in claim 33 corresponding to cancelled claim 16 and in claim 39 corresponding to cancelled claim 20 is a fucoidan derived from Kjellmaniella crassifolia.

The Examiner points out on page 7 of the outstanding Office

Action that "PARISH teaches that administration of fucoidan can
. '

prevent experimental allergic encephalomyelitis, . . ." However,

as shown in Example 6 of the present specification, fucoidan has different structures depending upon its derivation, so that it is evident that their activities are different. Therefore, the action of the fucoidan derived from *Kjellmaniella crassifolia* cannot be anticipated by the above description.

Moreover, the Parish et al. reference only specifically describes the examination of antimetastatic and anticoagulant effects for the fucoidan derived from Fucus vesiculosus (See column 3, lines 9-10 and Example 1 of the Parish et al. reference). However, fucoidan derived from Kjellmaniella crassifolia of the inventions recited in claims 33 and 39 is clearly different than the fucoidan derived from Fucus vesiculosus of the Parish et al. reference. Therefore, the inventions of claims 33 and 39 cannot be anticipated by the teachings of the Parish et al. reference. Accordingly, the rejection of claims 14, 16, 20 and 21 under 102(e) over Parash et al. for the reasons set forth on page 7 of the Office Action should be withdrawn by the Examiner.

Rejection of Claims 14, 16, 20 and 21 Under 35 U.S.C. 102(a) Over Granert et al.

Claims 14, 16, 20 and 21 are rejected by the Examiner under 35 U.S.C. 102(a) as being anticipated by Granert et al. for the reasons set forth on pages 7-8 of the Office Action. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

Claims 14 and 21 are canceled and the rejection of these claims is thus moot.

Claim 33 relates to a method of treating or preventing a disease requiring regulation of cytokine production, a disease requiring nitrogen monoxide production, or an allergic disease, wherein the method comprises administering a fucoidan derived from Kjellmaniella crassifolia and/or a degradation product thereof. Claim 39 relates to a method for regulating cytokine production, inducing nitrogen monoxide production, suppressing allergy, or suppressing IgE production, wherein a fucoidan derived from Kjellmaniella crassifolia and/or a degradation product thereof is used as an effective ingredient.

Accordingly, the recitation of fucoidan in claims 33 and 39, corresponding to cancelled claims 16 and 20, respectively, relates to fucoidan derived from *Kjellmaniella crassifolia*.

In contrast to the claimed invention, Granert et al. specifically describes that fucoidan manufactured by Sigma Chemical Co., Ltd, St. Louis, MO (page 2072, left column, line 18) inhibits the release of TNF- α and IL-1 (see for instance, Table 1.). Applicants have studied how the fucoidan manufactured by Sigma Chemical Co., Ltd, St. Louis, MO is As a result, Applicants deduced that the fucoidan of derived. the Granert et al. reference is derived from Fucus vesiculosus. Applicants evidence in support of this conclusion is Sigma's own publication. In this regard, the Examiner's attention is directed to the attached copy of the Catalog of 2000 Sigma Chemical Co., Ltd. listing their fucoidan. Applicants also provide a printout of the portion of Sigma's Catalog explaining their fucoidan. This information is obtained from Sigma's home page.

As a result, it is readily apparent that fucoidan derived from *Kjellmaniella crassifolia* of the present invention as recited in claims 33 and 39 is clearly different from fucoidan derived from *Fucus vesiculosus*. Therefore, the inventions recited in claims 33 and 39 are not anticipated by the teachings of the cited Granert et al. reference. Accordingly, the rejection of the claims over the Granert et al. reference should be withdrawn by the Examiner.

Rejection of Claims 14, 16, 20 and 21 Under 35 U.S.C. 102(b) Over KYODO NYUGYO KK (Japanese Patent Laid-Open No. 10-72362 (JP'362))

Claims 14, 16, 20 and 21 are rejected by the Examiner under 35 U.S.C. 102(b) as being anticipated by Kyodo Nyugyo KK for the reasons set forth on page 8 of the Office Action. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

Claims 14 and 21 are canceled. Also, the fucoidan recited in claims 33 and 39 corresponding to cancelled claims 16 and 20, respectively, relates to fucoidan derived from *Kjellmaniella* crassifolia.

The Examiner points out on page 8 of the outstanding Office Action that "KYODO NYUGYO KK teaches that administration of fucoidan can treat or prevent allergic disease and can suppress production of interleukin 4,..." However, the JP'362 reference only describes the function of fucoidan derived from Laminaria diabolica. Specifically, the JP '362 reference describes in paragraph [0008] thereof the following:

[Modes for Carrying out the Invention]

A. Method for Preparing Fucoidan and Fucoidan-Like Polysaccharide

Dry Laminaria diabolica is thinly sliced with scissors or the like, and 5-times by volume of deionized water is added thereto, and thereafter the mixture was heat-treated at 121°C for 15 minutes. The extract was made clear by centrifugation or filtration method, and then lyophilized. The lyophilized product was purified by ion-exchanged chromatography using DEAE Cellulofine (Seikagaku Kogyo), and each of the substances were identified by contents of fucose, uronic acid and sulfuric acid, and electrophoresis."

In contrast to the teachings of the JP '362 reference, fucoidan derived from *Kjellmaniella crassifolia* as recited in claims 33 and 39 is different from fucoidan derived from *Laminaria diabolica* of JP'362. Therefore, the inventions as recited in claims 33 and 39 are not anticipated by the teachings

of the JP '362 reference. Accordingly, the rejection of the claims over the JP '362 reference should be withdrawn by the Examiner.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant(s) respectfully petition(s) for a one month extension of time for filing a reply in connection with the present application, and the required fee of \$110.00 is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

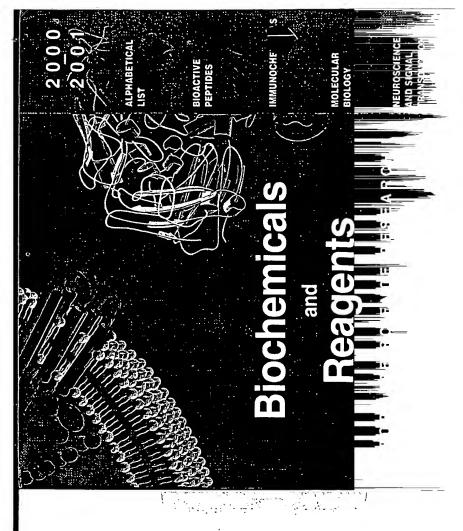
Marc S. Weiner, #32,181

P.O. Box 747

Falls Church, VA 22040-0747

1422-0514P (703) 205-8000

MSW/sh



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F 1002

PRODUCT NUMBER

F 1127

ALPHABETICAL LIST OF COMPOUNDS

112 Submitted of Health 112 Submitted of Health 112 Submitted of Health 113 Submitted of Health 113 Submitted 113
RUCTOSE_6-PHOSPHATE
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F 3627

F 1502

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Click Here

Product Number: F5631

Product Name: Fucoidan from Fucus vesiculosus

Preductinismesten/

Description

Certificate of Analysis Certificate of Origin

MSDS

Quidona

Print Preview Bulk Quote Ask A Scientist Synonyms: Fucoidin

MDL number: MFCD00131109

CAS Number: 9072-19-9

MDL Number: MFCD00131109

Storage Temp: RT

Comments:

A polysaccharide composed predominantly of sulfated fucose.

Quality note: Crude

Prepared by a modification of the method of Black, W.A.P., et al., J. Sci. Food Agri., 3,

122 (1952).

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Product Number: 47865

Product Name: Fucoidan from Fucus vesiculosus

Preductinismesten/

Description

Certificate of Analysis

MSDS

Englishe

Print Preview Bulk Quote Ask A Scientist Synonyms: Fucoidin

MDL number: MFCD00131109

CAS Number: 9072-19-9

MDL Number: MFCD00131109

Assay: 9-10% as sulfur Literature References:

1. R.M. Williams, R. Jones, FEBS Lett. 270, 168 (1990)

Comments:

BioChemika, 9-10% as sulfur

polysaccharide, consists predominantly of sulfated L-fucose

Probe of polysaccharide binding to proacrosin

by a modification of the procedure of W.A.P. Black et al., J.Sci.Food.Agr.

3 122 (1952)

0, 122 (1002)	
Extended specifications	
Water ≤15%	
Na 7-8%	

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